

## 21 CFR Part 11 compliance and solutions

Our first 21CFR Part 11 SCADA package was installed way back in 2007 in Serum Institute, Pune. We have over 12 years experience working with 21CFR systems in the industry. We understand and comply all URS's of 21CFR Part 11, USFDA and Eudralex. Along with automation and SCADA we also understand the challenges of IT infra and configuration requirements of the customer, which enables to comply 100% with the URS.

We help End Users and Original Equipment Manufacturers (OEM) in this industry to comply with the most stringent norms that 21CFRPart11 demands. We have absolute clarity on this subject and with our experience of working in the Life sciences industry for more than 20 years, we can deliver systems with no liability to the end user from auditors.

Security & E-Signatures features  
Audit and Alarm Reports  
Electronic Records, Batch Reports  
Auto Data Backup  
RAID Hardware

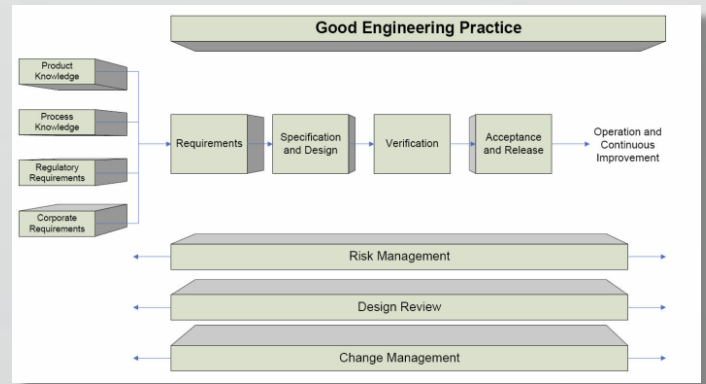
Validation Documentation  
IT System / OS Security Requirement  
Complete GAMP5 Implementation  
Signature Manifestations  
Custom Reports



**PINNACLE**  
INDUSTRIAL CONTROLS

## Domain Expertise

Solid Formulations  
Liquid Formulations  
Hi Purity Water Systems  
HVAC  
Sterilization, Cleaning Solutions



## Documentation

Compliance of the URS  
Functional Design Specifications (FDS)  
Screenshots of HMI  
Logic flow  
Valve matrix  
Security matrix  
System architecture  
Design Qualification (DQ)  
Installation Qualification (IQ)  
Operational Qualification (OQ)  
FAT (Factory Acceptance Test) Procedure  
Disaster Recovery Management  
Electrical Panel Drawings  
User Manuals



## Install Base

USV, Daman  
Mankind Pharma, Poanta Sahib  
Aurobindo, Hyderabad  
Strides Pharma,  
Bangalore/Singapore  
Alembic, Jarod  
Sun Pharma, Halol  
Alkem, Daman  
Wockhardt, Waluj/Daman  
Glenmark, Goa  
Shantha Biotech, Hyderabad  
Mylan, Pithampur  
Annora Pharma, Vizag  
Genesis, Hyderabad  
Granules India, Hyderabad

